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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,683	06/24/1999	GREGOR CEVC	35946-701.831	2670
21971 7590 11/29/2007 WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050			EXAMINER KISHORE, GOLLAMUDI S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 11/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/284,683

Applicant(s)

CEVC, GREGOR

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10-30-07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 106-110, 112-118, 120 and 121 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 106-110, 112-118, 120 and 121 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment dated 7-12-07 is acknowledged.

Claims included in the prosecution are 106-110, 112-118 and 120-121.

In view of the amendments, the 112, rejection and 102 rejections are withdrawn.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 116-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 106 recites the language 'consisting essentially of'; the dependent claim 116 which recites "vesicle further consists essentially of one or more consistency modifiers--" is inconsistent with the language in the parent claim.

#### **Claim Rejections - 35 U.S.C. § 103**

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

4. Claims 106-110, 112-118 and 120-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyas (Journal of micro encapsulation, 1995) or Hayward (5,585,109) or Sheffield (4,937,254) in combination with Mezei (4,897,269).

Vyas discloses topical application of liposomes consisting essentially of PC and diclofenac in PBS, pH 7.4 (abstract, Table 1 formulation L1).

Hayward discloses liposomal formulations containing soy lecithin and salicylic acid and a method of delivery to the skin. The carrier material is polymethacrylate gel. The pH is 6.5 to 7.5. The composition further contains antioxidants and preservatives and hydrocolloids (columns 3-7). What is lacking in Hayward is the use of claimed antioxidants and Stabilizers.

Sheffield teaches a method of topical administration of liposomal formulations containing phosphatidylcholine and NSAID. The method of administration is topically and either internally or externally which implies skin. The composition further contains PBS and hydrocolloids (col. 3, lines 7-56; col. 6, line 15 through col. 7, line 12, Examples 13-15).

What is lacking in Vyas, Hayward or Sheffield is the inclusion of benzyl alcohol.

Mezei while disclosing liposomal compositions teaches the addition of preservatives and antioxidants such as benzyl alcohol and tocopherol (abstract, Example 4 and col. 14, lines 42-63).

The addition of antioxidants and stabilizers in the compositions of Vyas or Hayward or Sheffield would have been obvious to one of ordinary skill in the art since such an addition would prevent oxidation of lipids and degradation by bacteria respectively as taught by Mezei. What is lacking in Hayward is the teaching of the use of synthetic phospholipid. However, since liposomes can be formed with either natural or synthetic phospholipids, it is deemed obvious to one of ordinary skill in the art to choose the desired source with a reasonable expectation of success. Hayward and Sheffield also lack the teaching of the application of the claimed amount of the liposomes on the skin surface. However, since the amount applied depends upon the condition to be treated and the severity of the condition, it is deemed obvious to one of ordinary skill in the art to manipulate this parameter to obtain the best possible results.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that none of the references teach or disclose vesicles comprising phenol, cresol or benzyl alcohol, much less a vesicle consisting essentially of or more phosphatidylcholines, a salt of one or more NSAIDs, and one more of phenol, cresol or benzyl alcohol. This argument is not persuasive. Hayward teaches the topical administration of Salicylic acid in liposomes containing lecithin (phosphatidylcholine). Instant claims recite 'buffers as aqueous medium and arginine taught by Hayward is routinely used as a buffer. The examiner cites US 2007/0243203 in this context (see 0344). Applicant's arguments that the salicylic acid compositions of Hayward are composed of only free salicylic acid. This argument is not persuasive. According to instant claim 108, the pH of the buffer is between 3-12, particularly between 6 and 8.

That means instant composition can include a pH less than neutral and therefore, even instant NSAIDs will be in protonated form. Although Hayward does not teach the encapsulation of other NSAIDs, it would have been obvious to one of ordinary skill in the art to encapsulate any NSAID with a reasonable expectation of success.

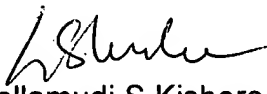
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK